**UNITED STATES DISTRICT COURT FOR
THE EASTERN DISTRICT OF VIRGINIA
(Alexandria Division)**

TRIANTAFYLLOS TAFAS, **Plaintiff,** **v.** **JON W. DUDAS, in his official capacity as Under-Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office, and the UNITED STATES PATENT AND TRADEMARK OFFICE,** **Defendants.**	**CIVIL ACTION: 1:07cv846 (JCC/TRJ) and Consolidated Case (below)**
SMITHKLINE BEECHAM CORPORATION, **Plaintiff,** **v.** **JON W. DUDAS, in his official capacity as Under-Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office, and the UNITED STATES PATENT AND TRADEMARK OFFICE,** **Defendants.**	

PLAINTIFF TRIANTAFYLLOS TAFAS' MEMORANDUM OF LAW IN OPPOSITION TO DEFENDANTS' MOTION TO STRIKE

PRELIMINARY STATEMENT

The plaintiff, Triantafyllos Tafas ("Dr. Tafas") respectfully submits this Memorandum of Law in Opposition to Defendants' Motion to Strike certain summary judgment exhibits filed by Plaintiff Dr. Tafas, *Amicus Curiae* Dr. Ron D. Katznelson ("Dr. Katznelson") and *Amici* Polestar Capital Associates, LLC ("Polestar") and Norsemen Group, LLC (sometimes collectively referred to herein as the "Polestar *Amici*") dated January 22, 2008 (Docket No. 249-250).

Dockets.Justia.com

As is set forth more particularly below, Defendants' Motion to Strike must be denied because none of the so-called "extra-record" declarations or exhibits are being offered for any purpose inconsistent with the APA. Dr. Tafas, Dr. Katznelson and the Polestar *Amici* have offered this evidence for purposes of explaining and/or critiquing the existing administrative record for the Court. There is no legal support for the USPTO's argument that Dr. Tafas, *Amicus Curiae* Dr. Katznelson or the Polestar *Amici* should be completely gagged from using extra-record exhibits to illustrate for the Court the numerous deficiencies, inconsistencies, contradictions, and faulty reasoning within the administrative record, all of which is reflective of arbitrary and capricious rulemaking in violation of the APA and Regulatory Flexibility Act (RFA).

ARGUMENT

Point I

THERE IS NO IMPERMISSIBLE USE OF EXTRA-RECORD EVIDENCE

A. Extra-Record Evidence May be Cited to Prove Arbitrary and Capricious Agency Action or Constitutional Violations.

The standard of judicial review here is governed by 5 U.S.C. § 706. An agency's decision is arbitrary and capricious under the APA if the agency has relied on factors which Congress has not intended it to consider; entirely failed to consider an important aspect of the problem; offered an explanation for its decision that runs counter to evidence before the agency; or, provided an explanation that is so contrary to the evidence or implausible that it could not be ascribed to a reasonable difference in view. Motor Vehicle Mfrs. Ass'n of U.S., Inc., v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983). In making its determination as to whether rule making by an administrative agency is arbitrary, capricious, or an abuse of discretion, a court should consider whether the agency's decision was based on an evaluation of the relevant factors and whether there has been a clear error of judgment. Bowman Transp., Inc. v. Arkansas-Best Freight Sys., Inc., 419 U.S. 281, 285 (1974).

In more common legal parlance, "arbitrary and capricious" behavior is defined as follows:

> **Arbitrary and Capricious**. Characterization of a decision or action taken by an administrative agency…meaning willful and unreasonable action without consideration or in disregard of facts or without determining principle.

BLACK'S LAW DICTIONARY, 5th Ed. at p. 96 (1979)(Citations Omitted)(Emphasis Added).

> **Arbitrary.** Means in an "arbitrary" manner, as fixed or done capriciously or at pleasure. Without adequate determining principle; not founded in the nature of things; non-rational; not done or acting according to reason or judgment; depending on the will alone; absolutely in power; capriciously; tyrannical; despotic...' not governed by any fixed rules or standard. Ordinarily, "arbitrary" is synonymous with bad faith or failure to exercise honest judgment and an arbitrary act would be one performed without adequate determination of principle and one not founded in nature of things.

Id. at p. 96 (Citations Omitted)(Emphasis Added).

The APA's standard of review, while deferential, "in no way requires the Court to 'rubber stamp' an agency action …. On the contrary, the Court must 'immerse' itself in the evidence in order to 'determine whether the agency decision was rational and based on consideration of the relevant factors.'" Ohio Valley Envtl Coalition v. U.S. Army Corps of Eng'rs, 479 F.Supp.2d 607, 621 (S.D. W.Va. 2007), quoting Ethyl Corp. v. EPA, 541 F.2d 1, 36 (D.C. Cir. 1976). Although the Court's review is based on "the [entire] administrative record[,] it may, when necessary, consider evidence outside the record to determine whether the agency has considered all relevant factors or to explain technical terms or complex subject matter." Id. at 622. (footnote omitted).

Administrative action that is irrational, or not based on relevant factors, is arbitrary and capricious. Commonwealth of Pennsylvania Dept. of Pub. Welfare v. U.S. Dept. of Health and Human Serv., 101 F.3d 939, 943 (3d Cir. 1996); Northwest Pipeline Corp. v. FERC, 61 F.3d 1479, 1486 (10th Cir. 1995)(administrative agency decision may be arbitrary and capricious for purposes of judicial review if it fails to consider important relevant factors); Thompson v. Clark, 741 F.2d 401, 405 (D.C. Cir. 1984)(a rule must be set aside if data in regulatory flexibility analysis or anywhere else in the rule making record demonstrates that the rule constitutes such an unreasonable assessment of social costs and benefits as to be arbitrary and capricious); Defenders of Wildlife v. U.S. Environmental Protection Agency, 420 F.3d 946, 959 (9th Cir. 2005) (internally contradictory agency reasoning renders resulting action arbitrary and capricious under APA.)

In order to satisfy this exacting standard of review, a plaintiff in an APA judicial review case necessarily must be permitted to critique and impeach the various conclusions, assumptions, contradictions, incongruities, faulty reasoning, ambiguities, etc. contained within the agency's stated reasons or rule making record.

Of course, common sense and experience dictates that no administrative agency is going to affirmatively state that its rule making was promulgated in disregard of important facts, without principle or in bad faith. In the same vein, an agency is exceptionally unlikely to volunteer that it intentionally, negligently or inadvertently failed to factor all information that the agency intentionally, negligently or inadvertently failed to consider an important aspect of a problem as part of its rulemaking. These are all deficiencies in the rule making process that need to be inferred, which necessarily will often involve juxtaposing self-serving agency statements in the record with contrary data and information from outside the record.

Nonetheless, the USPTO maintains in its motion to strike that Tafas' "arbitrary and capricious" arguments improperly rely on "extra-record" evidence and, therefore, should be ignored. Defendants' arguments are calculated to try and insulate its rule making from any challenge by muzzling Dr. Tafas and the relevant *Amici* from offering so called "extra-record information" to critique or impeach the USPTO's administrative record. It is apparent that the USPTO is upset that Dr. Tafas and the A*mici* have the temerity to attempt to criticize and impeach the USPTO's stated reasons, assumptions, data and methodologies and, in the process, brought to bear compelling extrinsic evidence to demonstrate the arbitrary and capricious nature of the USPTO's Final Rules.

The USPTO contends that that plaintiffs in an APA case should be required to simply accept as true at face value every self-serving agency statement in the administrative record (regardless of how specious, vapid or erroneous the reasoning) and may not seek to illustrate any inadequacies, inconsistencies, incompleteness or flawed reasoning within the record by citing to contrary extrinsic facts or data points. Applying the USPTO's twisted and extreme logic, assuming arguendo, for sake of example only, that the USPTO had asserted in its Notice of Rule Making that 2+2=5 or that the earth was flat rather than round, then the USPTO's view would apparently be that Dr. Tafas must simply accept such absurd propositions as true and that he would be precluded from introducing testimony from mathematicians and scientists to refute these type of ludicrous assertions.

Fortunately, the USPTO has grossly misinterpreted the operative law. As set forth more particularly below, courts routinely permit plaintiffs in APA judicial review cases to utilize extrinsic evidence and expert opinion to explain the record, as well as to critique and to highlight inadequacies, contradictions and faulty assumptions or data contained within an existing administrative record.

First, the USPTO entirely ignores Federal Rules of Evidence 401, 402, 607, 611(b) and 613(b), which allow for the admissibility of relevant evidence, impeachment and cross examination:

> **Rule 401. Definition of "Relevant Evidence"**
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> "Relevant evidence" means evidence having any tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence.

FRE 401.

> **Rule 402. Relevant Evidence Generally Admissible; Irrelevant Evidence Inadmissible**
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> All Relevant Evidence is admissible, except as otherwise provided by the Constitution of the United States, by Act of Congress, by these rules, or by other rules prescribed by the Supreme Court pursuant to statutory authority. Evidence which is not relevant is not admissible.

FRE 402 (Emphasis Added).

There is no exception in the Federal Rules of Evidence exempting APA cases. Even assuming *arguendo* that Tafas is not permitted to use extra-record evidence to supplement the record *per se*, this does not by extension mean that Tafas is precluded from citing to extrinsic matter outside the record to **impeach** the credibility or reasoning in the record as part of demonstrating "arbitrary and capricious" rule making.

Along the same lines, numerous courts have recognized, including this Court in Tafas v. Dudas, 511 F.Supp.2d 652 (E.D.V.A. 2007)("Tafas I"), that expert testimony may properly be admitted pursuant to Rules 702 and 703 of the Federal Rules of Evidence in an APA proceeding for the purpose of helping to explain and interpret the administrative record, as well as to provide the Court with the necessary context and understanding to consider APA challenges, particularly those involving substantial complexity or highly specialized subject matter:

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.
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> However, "[e]ven in APA record review cases, circumstances may justify expanding the record or permitting discovery," including "such a failure in the record to explain administrative action as to frustrate judicial review, the agency's reliance on materials or documents not included in the administrative record, or the need to supplement the record to explain or clarify technical terms or other difficult subject matter included in the record." *Id.* at 477 (internal citations omitted); see also Public Power Council v. Johnson, 674 F.2d 791, 793-94 (9th Cir.1982) (holding that "there may be circumstances to justify expanding the record or permitting discovery," including "ascertaining whether the agency considered all the relevant factors or fully explicated its course of conduct or grounds for decision," situations "when it appears the agency has relied on documents or materials not included in the record," and other circumstances as "necessary to permit explanation or clarification of technical terms or subject matter involved in the agency action under review" as "background information").
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> Not only are there situations in which external information can be helpful to the Court, but the D.C. Circuit has pointed out that it can be reversible error for a district court to avoid going outside the administrative record in some situations. Esch v. Yeutter, 876 F.2d 976, 992 (D.C.Cir.1989). It recognized that extra-record evidence can be important in scenarios "when a case is so complex that a court needs more evidence to enable it to understand the issues

> clearly" and "in cases where relief is at issue, especially at the preliminary injunction stage," among others. Id. at 991.

Tafas I, 511 F.Supp.2d at 659-663.

As noted in the seminal case of Esch v. Yeutter, 876 F.2d 976, 991 (D.C. Cir. 1999), courts have developed a number of exceptions[1] permitting the use of extra-record evidence, such as:

> (1) when agency action is not adequately explained in the record before the court; (2) when the agency failed to consider factors which are relevant to its final decision; (3) when an agency considered evidence which it failed to include in the record; (4) when a case is so complex that a court needs more evidence to enable it to understand the issues clearly; (5) in cases where evidence arising after the agency action shows whether the decision was correct or not; (6) in cases where agencies are sued for a failure to take action; (7) in cases arising under the National Environmental Policy Act; and (8) in cases where relief is at issue, especially at the preliminary injunction stage.

Id. at 991 (emphasis added).

As reflected in the numerous persuasive cases cited below, Dr. Tafas, *Amicus Curiae* Dr. Katznelson and the Polestar *Amici* are entirely within their rights in offering extrinsic evidence (including expert analysis) to address, explain and critique the complex economic, statistical and technical issues raised in the USPTO's stated reasons and administrative record in support of Plaintiffs' legal arguments that the Final Rules are arbitrary and capricious, unconstitutional and promulgated contrary to the Regulatory Flexibility Act.

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[1] A court may go beyond the administrative record where: 1) an agency's failure to explain its action effectively frustrates judicial review; 2) it appears that the agency relied on materials not included in the record; 3) technical terms or complex subjects need to be explained; or 4) there is a strong showing of agency bad faith or improper behavior. See e.g., National Resources Defense Council v. U.S. EPA, 2005 WL 1241904 *9 (D. Md. 2005).

For example, American Canoe Ass'n, Inc. v. EPA, 46 F.Supp.2d 473, 477 (E.D.Va.1999) and Fort Sumter Tours v. Babbitt, 66 F.3d 1324, 1336 (4th Cir.1995) both stand for the proposition that a plaintiff in an APA case may present extra record evidence, inter alia, in complex cases to explain or critique technical issues or agency statistical analysis in the administrative record.

Similarly, in Conservation Law Foundation of New England, Inc. v. Clark, 590 F.Supp. 1467, 1474 (D. Mass. 1984), the court permitted the administrative record to be supplemented with extra record documents and expert affidavits when the record was "self-serving, incomplete or unclear", as well as, inter alia, under the exception that allows supplementation of the record to show factors the agency should have considered, but did not:

> It will often be impossible, especially when highly technical matters are involved, for the court to determine whether the agency took into consideration all relevant factors unless it looks outside the record to determine what matters the agency should have considered but did not. The court cannot adequately discharge its duty to engage in a "substantial inquiry" if it is required to take the agency's word that it considered all relevant matters.
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> In the instant case, it is arguable that the Park Service failed to consider adequately whether extensive ORV use of the Seashore, even if ecologically compatible, was an "appropriate public use" as mandated by the Seashore Act. Therefore, the court will admit documentary evidence that bears on this issue, including professional articles, expert affidavits, and figures on Cape Cod beach visitation.
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> * * * *:
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> If the reviewing court finds it necessary to go outside the administrative record, it should consider evidence relevant to the substantial merits of the agency action only for background information ... or for the limited purposes of ascertaining whether the agency considered all the relevant factors or fully explicated its course of conduct or grounds of decision. Consideration of the evidence to determine the correctness or wisdom of the agency's

> decision is not permitted, even if the court has also examined the administrative record. If the court determines that the agency's course of inquiry was insufficient or inadequate, it should remand the matter to the agency for further consideration and not compensate for the agency's dereliction by undertaking its own inquiry into the merits.

Id. at 1475. (Emphasis Added)(Citations Omitted). The Conservation court also permitted the so called extra record evidence because it was helpful in evaluating highly complex matter in the rule making record:

> Finally, a third exception permits introduction of evidence outside the record to explain an unclear or technical record. Ass'n of Pacific Fisheries v. EPA, 615 F.2d 794, 811 (9th Cir.1980) (post-decision studies "helpful in understanding the problems faced by the [EPA] and the methodology it used to resolve it ... [and] can be deemed a clarification or an explanation of the original information before the Agency"); Independent Meat Packers Ass'n v. Butz, 526 F.2d 228, 239 (8th Cir.1975). In this case the court is faced with matters of a highly technical nature particularly with respect to the effect of ORV's on dune physiography, vegetation, and aesthetics. The court will accordingly consider reports, affidavits, articles, and photographs submitted by the parties that tend to shed light on these technical matters.

Id. at 1475.

Likewise, in Citizens for Environmental Quality v. U.S., 731 F.Supp. 970 (D.Colo. 1989), which involved judicial review of an administrative decision to issue a comprehensive land management resource plan for a national forest, the court ruled that affidavits of experts on the use of computer models and forest planning were admissible, even though not in the administrative record, where the affidavits were helpful to the court's understanding of complex issues presented in the case, illuminated information contained in the administrative record, and served as points of reference therein reasoning:

> Judicial review of LRMPs [comprehensive land resource management plans for national forest] is unlike the review of typical agency decisions. [The court] must consider the technical complexity of the issues involved, and the possibility that years of

> costly research and planning may be undone in the event of a remand to the agency … [The court] must resist the temptation to "rubber stamp" agency decisions in the face of complex issues, and act to ensure that Forest Service decisions meet the required standards of regularity and rationality.

Id. at 983.

Extrinsic evidence and expert analysis may be offered to explain and critique the agency's rulemaking and to highlight the failure of any analysis contained within the produced record to adequately address relevant factors (such as reasonable alternatives) that should have been considered and/or if potential serious criticisms with the agency's stated rationale were seemingly "swept … under the rug." See e.g., National Audubon Society v. U.S. Forest Serv., 46 F.3d 1437, 1447 (9th Cir.1993); County of Suffolk v. Secretary of the Interior, 562 F.2d 1368, 1384-85 (2d Cir.1977); Lee v. U.S. Air Force, 354 F.3d 1229, 1242 (10th Cir. 2004)(when "we are faced with an agency's technical or scientific analysis, an initial examination of the extra-record evidence in question may aid us in determining whether these circumstances are present. As a number of other circuits have explained, such an initial review may illuminate whether 'an [agency] has neglected to mention a serious environmental consequence, failed adequately to discuss some reasonable alternative, or otherwise swept stubborn problems or serious criticism ... under the rug'"); U.S. v. Akzo Coatings of America, Inc., 949 F.2d 1409, 1428 (6th Cir. 1991)("Akzo") (in CERCLA action, the Sixth Circuit found that the district court had improperly refused to accept expert's affidavit on ground that it was not part of the administrative record; affidavit should have been admitted into evidence for the limited purpose of determining the adequacy of the EPA's decision so long as the court is careful not to change the character of the hearing from one for review to a trial de novo).

Still other cases allow extra-record information to be considered by a reviewing court where such information takes the form of newly discovered extra-record evidence which undermines the soundness of the agency's decision. See Akzo, 949 F.2d 1409, 1429 (6th Cir.1991) (finding that "sound principles of justice cannot allow a reviewing court to close its eyes and ears to the new evidence"); Sierra Club v. U.S. Army Corps of Engineers 935 F.Supp. 1556, 1567 (S.D.Ala.1996) (the Court allowed plaintiffs to expand the administrative record to include three post-decision statements because they fell under the "newly discovered evidence" exception in Akzo and also allowed plaintiffs to supplement the record with two post-decision letters because they fell under the "swept under the rug" exception in National Audubon).

Finally, due to the need for the Court to make an "an independent assessment of a citizens' claim of constitutional right", this Court has already opined that APA plaintiffs adjudicating constitutional claims are permitted to submit evidence that was not part of the agency's administrative record. Tafas v. Dudas, 2008 WL 112043 at p. 12 (E.D.VA. Jan. 9, 2008)("Tafas II")(citations omitted). Thus, in all events the so called extra-record materials in dispute here may be admitted in support of Dr. Tafas' constitutional claims.

B. The Court Should Not Strike The Declarations of Dr. Robert Fenili and Dr. Ron Katznelson.

The USPTO asserts that the declarations of Dr. Robert Fenili, and Dr. Ron Katznelson (particularly his appendices A-E to his Exhibit 1 declaration of his *amicus* brief), should be stricken in respect of Dr. Tafas' use of the same in support of his RFA arguments. (Def. Mem. In Support of Motion to Strike at 8). No parallel assertion is made with respect to the declaration of Dr. Belzer found at exhibit 21 to the Polestar *Amici* brief, which also is used by

Dr. Tafas in his RFA arguments, although the USPTO asserts that such declaration should be more generally stricken concerning Dr. Tafas' arbitrary and capricious arguments. Id. at 7.

The USPTO relies upon the Court's opinion in Tafas II, which overruled Dr. Tafas' Objection to Magistrate Jones' discovery order denying Dr. Tafas and GSK discovery for purposes of completing the administrative record (Id. at 6, 8), to suggest that the Court has made a final determination. As such, the USPTO contends that Dr. Tafas may not seek to introduce any documents or other evidence in the summary judgment phase of the case extrinsic to the USPTO's own self-made administrative record -- either to impeach statements made therein or, for purposes of permissible forms of supplementation allowed by the case law in APA cases. Of course, the USPTO is mixing apples and oranges. No such determination has yet been made by the Court and the prior discovery decision and scheduling order is not "law of the case" and/or dispositive of the merits of the case on summary judgment.

The USPTO cites to language in Tafas II emphasizing that the RFA imposes only "procedural requirements" while giving lip service to the Court's recognition that any RFA certification must be put forth as a "reasonable, good faith effort." Id. at *9. The USPTO entirely ignores, however, that it is a lack of "reasonable[ness]" concerning the USPTO's certification of no SEISNE ("significant economic impact on a substantial number of small entities") that Dr. Tafas, Dr. Fenili and Dr. Katznelson (and although not disputed in the context of the RFA, Dr. Belzer) contest in their respective declarations. Of course, this is highly significant because the USPTO was able to evade the statutory requirement that it conduct both an initial and final formal RFA analysis based on its flimsy no SIENSE certifications.

Dr. Tafas and the *Amici* are not precluded from presenting evidence demonstrating that the USPTO's no SEINSE certifications were predicated on unreasonable assumptions, or that the underlying analysis leading to the certification was cursory, threadbare and unreasonable. See, e.g., North Carolina Fisheries Ass'n v. Daley, 16 F.Supp.2d 647, 653 (E.D.Va. 1997) (Judge Doumar, after reviewing the agency's own guidelines for a no SEISNE certification, Id. at 652, and after allowing the testimony of "some 100 North Carolina fisherman" as to the effect that there was a significant economic impact, finding that the agency's no SEISNE certification to be "arbitrary and capricious" in that the agency had "entirely failed to consider an important aspect of the problem." Id. at 653 (citing to Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983)); see also, Southern Offshore Fishing Assoc. v. Daley, 995 F.Supp. 1411 (M.D. Florida 1998) (Judge Merryday allowing extra-record affidavits on the issue of whether the agency had "failed to consider relevant factors in framing [the] regulatory decision," noting that "[c]onsideration" of the same was "the only method of testing allegations that the government failed to allow sufficient notice and comment [concerning that basis of such certification] in the rulemaking process." Id. at 1436, fn. 34. The Court found that on the basis of the entire record, the no SEISNE certification failed to satisfy APA standards and RFA requirements, noting that the agency's failure to provide sufficient notice and comment on its analysis to the public thereby prohibited the public from "engag[ing] the agency in the sort of informed and detailed discussion that has characterized this litigation." Id. at 1436); National Ass'n of Psychiatric Health Sys. V. Shalala, 120 F.Su..2d 33 (D.D.C. 2000) (Judge Kessler finding that an agency's certification of no SEISNE to be "severely lacking," failing to "properly access the impact the final rule would have on small entities," and to "consider other significant alternatives to the rule," and to demonstrate, overall, a failure to be a "reasonable good-faith effort to canvass major options and weigh their probable effects." Id. at 42.).

As iterated by the U.S. Supreme Court in Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Ins. Co., 463 U.S. 29, 43 (1982), arbitrary and capriciousness is demonstrated when an agency relied on improper factors, failed to consider pertinent aspects of the problem, offered a rationale contradicting the evidence before it, or reached a conclusion so implausible that it cannot be attributed to a difference of opinion or the application of the agency expertise.

Here, the declarations of Dr. Fenili and Dr. Belzer, as well as the exhibit papers of Dr. Katznelson's declaration (Exhibit 1 to his *amicus* brief), demonstrate arbitrary and capriciousness with respect to the USPTO's no SEISNE certification by pointing out, among other things, the USPTO's reliance on entirely improper data; the USPTO's failure to consider pertinent aspects of the economic impact on a substantial number of small entities; the fact that the USPTO offered a rationale contradicting the evidence before it; and, that the USPTO's conclusion of no SEISNE is so implausible that it cannot be attributed to a difference of opinion or the application of agency expertise. [2]

The analyses of Dr. Fenili, Dr. Katznelson, and Dr. Belzer are also directed to showing the statistical invalidity of the evidence used by the USPTO in its no SEISNE certification. Further such analyses are pointed directly at the exemptions set forth in American Canoe Association, Inc. v. U.S. EPA, 46 F.Supp.2d 473 (E.D.Va. 1999), wherein Judge Ellis found "circumstances may justify expanding the record or permitting discovery," noting some circumstances, in a non-exclusive manner ("such" as) "a failure in the record to explain administrative action as to frustrate judicial review, the agency's reliance on materials or documents not included in the administrative record, or the need to supplement the record to explain or clarify technical terms or other difficult subject matter included in the record."

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[2] As set forth in Fort Sumter Tours, Inc. v. Babbitt, 66 F.3d 1324 (4^{th} Cir. 1995)("Fort Sumter") the burden is on the agency "to establish statistical validity of the evidence before it prior to reaching conclusions on that evidence," and it is the burden of the person challenging such conclusions to show that the agency's actions in such regard were arbitrary and capricious. Id. at 1336 (ultimately denying discovery because the reports which were sought were publicly available and were listed by the agency in a response to the challenger's FOIA request before the comment and notice period).

Here, Dr. Fenili's Declaration does not cite to any document outside of the administrative record, except that he looks at the entire volume of work in the 2005 AIPLA Economic Report a portion of which is recited by the USPTO at A04113 – A04332. Dr. Fenili does this to determine if the USPTO used data from the Report for a purpose other than what it was developed for by the authors of the work. This is entirely appropriate. As stated by the 4th Circuit Court of Appeals in Fort Sumter, 66 F.3d 1324, 1335 (4th Cir. 1995), "[a]n agency's use of a study that is designed for a purpose other than that for which it is used by the agency, and 'which is limited and criticized by its authors on points essential to its use sought to be made of it," may be considered arbitrary and capricious."

It is noted that the author of the AIPLA Economic Report, *Amicus Curiae* AIPLA, itself indicates at pages 11–12 of its own *amicus* brief that the data used by the USPTO in making its ESD cost estimates does not correspond to the "patentability search" referenced in the report but most closely paralleled that of a validity/invalidity opinion which per patent was multiple of times more expensive. Thus, Dr. Fenili's review of the entire volume of the work in his analysis is pertinent, and wholly supportable.[3] Dr. Fenili's Declaration is exactly the type of explanation and critique of complex and technical subject matter in an administrative record as has been expressly sanctioned by the case law. [4] (See also American Canoe and related cases, infra, at pp. 8).

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[3] Dr. Tafas categorically rejects the USPTO's snide insinuation that Dr. Fenili is not independent or biased based his association with a Kelley Drye & Warren LLP affiliate. Dr. Fenili conducted a thorough and exacting independent analysis and his conclusions are well supported. In any event, any USPTO claims of bias go to the weight that the Court chooses to give Dr. Fenili's expert views and not their admissibility.

As is more particularly set forth in his Declaration, Dr. Fenili concluded that major conclusions in the RFA's Certification Analysis were: flawed; made without adequate support or documentation; did not rest upon firm foundations; and that there was no basis or supporting data in the administrative for many assumptions used in the calculations that lie behind many of the findings in the USPTO's RFA Certification Analysis. (Fenili Decl., ¶¶ 7-8). Dr. Fenili concluded that that the new Final Rules would have a significant and disproportionate effect on small entities (contrary to the USPTO's RFA certification). (See Fenili Decl., ¶¶ 25-26).

More specifically, Fenili opined that: 1) the conclusions of the USPTO RFA Certification Analysis depend on data and assumptions that have no support in the administrative record; (2) the USPTO RFA Certification Analysis does not take into account many costs entailed in filing an Examination Support Document; (3) the USPTO RFA Certification Analysis includes data that has been incorrectly counted and improperly assembled; (4) even if one adopts all figures adopted by the USPTO in its analysis, standard economic models that calculate the effect of the Rules indicate that a substantial number of small entities will be significantly economically impacted by the new rules even with respect to the USPTO's standards for such a

[4] The record is appropriately supplemented by Mr. Fenili's declaration because it meets several of the exceptions to the general rule regarding limitations to the administrative record outlined in Esch v. Yeutter, 876 F.2d 976 (D.C.Cir.1989), for instance "(1) when agency action is not adequately explained in the record before the court; (2) when the agency failed to consider factors which are relevant to its final decision; . . . (4) when a case is so complex that a court needs more evidence to enable it to understand the issues clearly . . ." Amfac Resorts, LLC v. U.S. Dept. of Interior, 143 F. Supp. 2d 7, 12 (D.D.C. 2001) (paraphrasing Esch, 876 F.2d at 991-92). However, all the flaws in the USPTO's analysis are apparent within the record itself, albeit the full suite of problems take some elucidation.

finding; and (5) appropriate analysis indicates that small entities will be significantly, disproportionately affected by the new rules in comparison with large entities. (See Fenili Decl. at ¶¶ 3-26).

Moreover, under the applicable APA "arbitrary and capricious" standard, the USPTO's no SEISNE certification was improper for, among others, the following reasons: (1) the USPTO made assumptions that had a tendency to downplay or hide the economic impacts; (2) the USPTO underestimated the number of affected small entities, inappropriately defined the universe of small entities, and failed to recognize the disproportionate impacts on this sector; and (3) the USPTO used faulty data and data generated for an entirely different purpose, making it misleading based on the record sources from which they were derived. (Fenili Decl., ¶¶ 3-26).

In the interests of brevity, Dr. Tafas respectfully refers the Court back to the Fenili Declaration and Dr. Tafas' various memoranda of law filed in connection with the summary judgment proceedings for a full write-up of the myriad of un-rebutted deficiencies and other problem areas Dr. Fenili identified in the USPTO's RFA Certification Analysis. (See Tafas Mem. In Support of Summary Judgment at pp. 39-45 (No. 141); Tafas Mem. In Opp. To Def. Summary Judgment Motion at pp. 9-10; 28-33 and 36-40); Tafas' Reply Mem. In Supp. Of Summary Judgment at pp. 37-41).

Similarly, Dr. Katznelson's *amicus* brief in respect of his commentary on the RFA certification of no SEISNE, and the exhibits corresponding to his statements, in particular appendix E, clearly meet at least two of the exemplary circumstances allowing the use of extrinsic information in American Canoe, in particular "the need to supplement the record to explain … difficult subject matter included in the record." For example, Dr. Katznelson explains how a 15/75 claim application is not equivalent to three 5/25 claim applications, as well as how to appropriately calculate the number of small entities in a class. See, Southern Offshore Fishing Assoc. v. Daley, 955 F.Supp. 1411, 1435 - 36 (M.D. Florida 1998) wherein the Court in part found the agency's SEISNE certification to be defective in that it had inappropriately characterized the affected universe of small entities), and to fill in a "a failure in the record to explain administrative action as to frustrate judicial review" in dealing with important issues that the USPTO failed to analyze or consider in respect its rulemaking. See also, North Carolina Fisheries Ass'n v. Daley, 16 F.Supp.2d 647, 653 (E.D.Va. 1997) (Judge Doumar allowing supplementation of the record to show that the agency "entirely failed to consider an important aspect of the problem", including failing to consider the disproportionate effect the Final Rules would have on small entities, emerging growth industry , and segments and domestic inventors, ignoring the new presumption of patentably indistinct claims in its economic analysis, and failing to take into account in a reasonable manner all the factors involved in generating a Examination Support Document under its New Rules).

At pages 24–25 of his declaration, Dr. Belzer addresses the USPTO's no SEISNE certification, for which the underlying analysis was supposedly performed by the USPTO's outside contractor, ICF, without reference to documents outside of the record produced by the USPTO as the administrative record. Dr. Belzer's statements clearly point out failures in the record to explain administrative action so as to frustrate judicial review, as well as supply needed information to explain or clarify technical terms or other difficult subject matter included in the record. Thus, Dr. Belzer's analysis is entirely permissible within the previously discussed exceptions to the administrative record rule and there is no basis to strike his critique of the USPTO's RFA Certification Analysis.

The Polestar *Amici* also do an excellent job of demonstrating that the USPTO's rule making was arbitrary and capricious. For example, the Polestar *Amici* demonstrate that the USPTO declined to make essential information available to the public during its rulemaking procedure; failed to disclose information about its computer models by which the USPTO purported to analyze its data; failed to consider important aspects of its backlog; failed to properly consider the effect of its rules on its own revenues and the cost burden on the public, and relied on factors which Congress did not intend. (See Tafas Reply Brief at pp. 28-32)(No. 263).

The Polestar *Amici* also specifically identify numerous documents found in the administrative record which go to data and assumptions used during the rulemaking process which were not made available to the public, as they should have been, during the rulemaking process. (See Tafas Reply Brief at pp. 28-32)(No. 263). The Polestar *Amici* and Dr. Belzer further illustrate how the USPTO has taken inconsistent positions with respect to the paperwork burden imposed by the new rules. (See Tafas Reply Brief at pp. 28-32)(No. 263). Again, all of this type of analysis is entirely permissible and consistent with the APA because it is either explanatory and/or impeaches the administrative record.

C. The Court Should Not Strike the Declarations of Dr. Tafas and Michael Rueda.

The Declaration of Michael Rueda in support of Dr. Tafas' summary judgment motion was filed for the limited purpose of either providing the Court with convenient access to certain pertinent documents from the administrative record, as well as to authenticate certain non-record documents cited in the various memoranda and/or declarations. There is no substantive expert testimony contained within the Rueda Declaration, which is entirely permissible (and necessary) for Dr. Tafas to authenticate the non-record documents that he is submitting to the Court for the limited purpose of impeaching the USPTO's rulemaking and demonstrating its arbitrary and capricious nature.

Dr. Tafas' Declaration describes the substantial injury Dr. Tafas' faces in the event that the Final Rules should be implemented, which is relevant both to impeach the USPTO's self-serving assertion that the Final Rules are merely procedural rules with little if any substantive adverse effect on patent applicants such as Dr. Tafas, as well as to rebut the USPTO's "off and on" arguments that Dr. Tafas lacks standing with respect to certain claims. (See Tafas Decl. ¶¶ 17-65). Dr. Tafas' declaration also cites to and appends certain non-record documents that impeach certain statements made in the USPTO's administrative record and RFA Certification Analysis, which again is permissible under the American Canoe line of cases.

Moreover, a substantial amount of the Tafas Declaration simply *explains* inconsistencies, deficiencies and other problem areas with the USPTO's Final Rules and the stated reasons for same. Thus, the Tafas Declaration should also be admissible for the reasons articulated in American Mining Congress v. Thomas, 772 F.2d 617 (10th Cir. 1985). In American Mining, the court denied a motion to strike references to extra record documents noting that there are exceptions to the administrative record rule, inter alia, including where the case is so complex and the record so unclear that the extra-record information would be helpful to the court in discharging its judicial review function. While the court ultimately declined to permit the plaintiff to supplement the record *per se* with the materials in question based on the peculiar facts of that case, it did refuse to strike the references to the documents viewing them "as substantially akin to the practice of citation to scientific treatises in ordinary civil cases." Id. at 627.

For all the foregoing reasons, the Rueda Declaration, Tafas Declaration and accompanying exhibits should not be stricken.

D. The Cases Cited By the USPTO Are Distinguishable.

The USPTO cites to three cases as support for its assertion that expert affidavits on the RFA should be struck as being irrelevant to the RFA, and "because they impermissibly introduce into the record materials that were not before the USPTO when it promulgated the Final Rules." (Def. Mem. In Support of Motion to Strike at 8). However, except for some skillful excerpting of isolated phrases in such cases, these cases do not stand for the USPTO's stated propositions.

For example, the USPTO cites to IMS v. Alvarez, 129 F.3d 618, 624 (D.C. Cir. 1997) suggesting it stands for the proposition that "affidavits that were not before the USPTO at the time it acted" should be stricken. In fact, in the IMS case (which was not a RFA case or a challenge to an agency rulemaking), the Court stuck the affidavits simply because they "provide[d] significant new information about circumstances surrounding … [a] contract" which the court held "should have been submitted to the agency before th[e] dispute reached the courts." *Id* at 623. The IMS case had nothing to do with expert testimony "to explain administrative action" so as not to "frustrate effective judicial review," which the Court found to be a valid reason for admitting affidavits (*Id.*) (an exception that Dr. Tafas asserts in respect of Dr. Fenili's affidavit in this complex RFA dispute).

Likewise, Envtl. Def. Fund, Inc. v. Costle, 657 F.2d 275 (D.C. Cir. 1981) did not review expert affidavits in respect of an RFA certification. Instead, the court struck four affidavits that were sought to be admitted into the case because the affidavits were directed solely at the "propriety of the agency action," that is, they pertained solely to an examination of "the propriety of the decision itself," which the court found "not relevant when reviewing informal agency action." Id. at 286 (fn. 37). The Envtl Def. Fund court distinguished this situation from one where the affidavit was "to explain the record where a failure to do so might frustrate effective judicial review," Id. at 286, fn. 36, which it found an appropriate situation for submitting an affidavit.

Lastly, Walter O. Boswell Mem'l Hosp. v Heckler, 749 F.2d 788 (D.C. Cir. 1984), like Alvarez and Envtl Def. Fund did not involve a challenge to a RFA certification. The Court denied the admission of affidavits that attempted to "summarize a study performed after … [a] published … final rule" that related to the "actual experience" of the affiants with respect to a "Malpractice Rule" passed by Health and Human Services that related to Medicare reimbursement of malpractice premiums paid by hospitals in respect to the treatment of Medicare patients. Id. at 793-794. The court struck these affidavits simply because the court deemed them to irrelevant "to determining the validity " of the Malpractice Rule. Id. at 794. It did not in any manner suggest that affidavits of parties in administrative rulemaking challenges submitted for the purpose of identifying arbitrary and capricious agency action should always be stricken as suggested by the USPTO in its supporting memorandum at page 8.

CONCLUSION

WHEREFORE, for all the foregoing reasons, Dr. Tafas respectfully moves the Court to sustain Dr. Tafas' Objection and to deny Defendants' Motion to Strike, along with such other, further and different relief as the Court deems just, equitable and proper.

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